

House File 597 - Reprinted

HOUSE FILE 597
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 200)

(As Amended and Passed by the House March 23, 2011)

A BILL FOR

1 An Act creating new procedures for external review of health
2 care coverage decisions by health carriers and including
3 transition and applicability provisions.

4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514J.101 Purpose — applicability.

2 The purpose of this chapter is to provide uniform standards
3 for the establishment and maintenance of external review
4 procedures to assure that covered persons have the opportunity
5 for an independent review of an adverse determination or final
6 adverse determination made by a health carrier as required
7 by the federal Patient Protection and Affordable Care Act,
8 Pub. L. No. 111-148, as amended by the federal Health Care and
9 Education Reconciliation Act of 2010, Pub. L. No. 111-152,
10 which amends the Public Health Service Act and adopts, in part,
11 new 42 U.S.C. § 300gg-19, and to address issues which are
12 unique to the external review process in this state.

13 Sec. 2. NEW SECTION. 514J.102 Definitions.

14 As used in this chapter, unless the context otherwise
15 requires:

16 1. "*Adverse determination*" means a determination by a health
17 carrier that an admission, availability of care, continued
18 stay, or other health care service that is a covered benefit
19 has been reviewed and, based upon the information provided,
20 does not meet the health carrier's requirements for medical
21 necessity, appropriateness, health care setting, level of care,
22 or effectiveness, and the requested service or payment for the
23 service is therefore denied, reduced, or terminated. "*Adverse*
24 *determination*" does not include a denial of coverage for a
25 service or treatment specifically listed in plan or evidence
26 of coverage documents as excluded from coverage, or a denial
27 of coverage for a service or treatment that has already been
28 received and for which the covered person has no financial
29 liability.

30 2. "*Authorized representative*" means any of the following:

31 a. A person to whom a covered person has given express
32 written consent to represent the covered person in an external
33 review.

34 b. A person authorized by law to provide substituted consent
35 for a covered person.

1 *c.* A family member of the covered person when the covered
2 person is unable to provide consent.

3 *d.* The covered person's treating health care professional
4 when the covered person is unable to provide consent.

5 3. "*Best evidence*" means evidence based on randomized
6 clinical trials. If randomized clinical trials are not
7 available, "*best evidence*" means evidence based on cohort
8 studies or case-control studies. If randomized clinical
9 trials, cohort studies, or case-control studies are not
10 available, "*best evidence*" means evidence based on case-series
11 studies. If none of these are available, "*best evidence*" means
12 evidence based on expert opinion.

13 4. "*Case-control study*" means a retrospective evaluation
14 of two groups of patients with different outcomes to determine
15 which specific interventions the patients received.

16 5. "*Case-series study*" means an evaluation of a series
17 of patients with a particular outcome, without the use of a
18 control group.

19 6. "*Certification*" means a determination by a health carrier
20 that an admission, availability of care, continued stay, or
21 other health care service has been reviewed and, based on
22 the information provided, satisfies the health carrier's
23 requirements for medical necessity, appropriateness, health
24 care setting, level of care, and effectiveness.

25 7. "*Clinical review criteria*" means the written screening
26 procedures, decision abstracts, clinical protocols, and
27 practice guidelines used by a health carrier to determine the
28 necessity and appropriateness of health care services.

29 8. "*Cohort study*" means a prospective evaluation of two
30 groups of patients with only one group of patients receiving a
31 specific intervention.

32 9. "*Commissioner*" means the commissioner of insurance.

33 10. "*Covered benefits*" or "*benefits*" means those health care
34 services to which a covered person is entitled under the terms
35 of a health benefit plan.

1 11. "*Covered person*" means a policyholder, subscriber,
2 enrollee, or other individual participating in a health benefit
3 plan.

4 12. "*Disclose*" means to release, transfer, or otherwise
5 divulge protected health information to any person other than
6 the individual who is the subject of the protected health
7 information.

8 13. "*Emergency medical condition*" means the sudden and, at
9 the time, unexpected onset of a health condition or illness
10 that requires immediate medical attention, where failure to
11 provide medical attention would result in a serious impairment
12 to bodily functions, serious dysfunction of a bodily organ or
13 part, or would place the person's health in serious jeopardy.

14 14. "*Emergency services*" means health care items and
15 services furnished or required to evaluate and treat an
16 emergency medical condition.

17 15. "*Evidence-based standard*" means the conscientious,
18 explicit, and judicious use of the current best evidence based
19 on the overall systematic review of the research in making
20 decisions about the care of individual patients.

21 16. "*Expert opinion*" means a belief or an interpretation
22 by specialists with experience in a specific area about
23 the scientific evidence pertaining to a particular service,
24 intervention, or therapy.

25 17. "*Facility*" means an institution providing health
26 care services or a health care setting, including but not
27 limited to hospitals and other licensed inpatient centers,
28 ambulatory surgical or treatment centers, skilled nursing
29 centers, residential treatment centers, diagnostic, laboratory
30 and imaging centers, and rehabilitation and other therapeutic
31 health settings.

32 18. "*Final adverse determination*" means an adverse
33 determination involving a covered benefit that has been upheld
34 by a health carrier at the completion of the health carrier's
35 internal grievance process.

1 19. *"Health benefit plan"* means a policy, contract,
2 certificate, or agreement offered or issued by a health carrier
3 to provide, deliver, arrange for, pay for, or reimburse any of
4 the costs of health care services.

5 20. *"Health care professional"* means a physician or other
6 health care practitioner licensed, accredited, registered, or
7 certified to perform specified health care services consistent
8 with state law.

9 21. *"Health care provider"* or *"provider"* means a health care
10 professional or a facility.

11 22. *"Health care services"* means services for the diagnosis,
12 prevention, treatment, cure, or relief of a health condition,
13 illness, injury, or disease.

14 23. *"Health carrier"* means an entity subject to the
15 insurance laws and regulations of this state, or subject
16 to the jurisdiction of the commissioner, including an
17 insurance company offering sickness and accident plans, a
18 health maintenance organization, a nonprofit health service
19 corporation, a plan established pursuant to chapter 509A
20 for public employees, or any other entity providing a plan
21 of health insurance, health care benefits, or health care
22 services. *"Health carrier"* includes, for purposes of this
23 chapter, an organized delivery system.

24 24. *"Health information"* means information or data, whether
25 oral or recorded in any form or medium, and personal facts or
26 information about events or relationships that relates to any
27 of the following:

28 a. The past, present, or future physical, mental, or
29 behavioral health or condition of a covered person or a member
30 of the covered person's family.

31 b. The provision of health care services to a covered
32 person.

33 c. Payment to a health care provider for the provision of
34 health care services to a covered person.

35 25. *"Independent review organization"* means an entity that

1 conducts independent external reviews of adverse determinations
2 and final adverse determinations.

3 26. "*Medical or scientific evidence*" means evidence found in
4 any of the following sources:

5 a. Peer-reviewed scientific studies published in or accepted
6 for publication by medical journals that meet nationally
7 recognized requirements for scientific manuscripts and that
8 submit most of their published articles for review by experts
9 who are not part of the editorial staff.

10 b. Peer-reviewed medical literature, including literature
11 relating to therapies reviewed and approved by a qualified
12 institutional review board, biomedical compendia, and other
13 medical literature that meet the criteria of the national
14 institutes of health's national library of medicine for
15 indexing in index medicus or medline, or of elsevier science
16 ltd. for indexing in excerpta medicus or embase.

17 c. Medical journals recognized by the United States
18 secretary of health and human services under section 1861(t)(2)
19 of the federal Social Security Act.

20 d. The following standard reference compendia:

21 (1) American hospital formulary service drug information.

22 (2) Drug facts and comparisons.

23 (3) American dental association accepted dental
24 therapeutics.

25 (4) United States pharmacopoeia drug information.

26 e. Findings, studies, or research conducted by or under
27 the auspices of federal government agencies and nationally
28 recognized federal research institutes, including any of the
29 following:

30 (1) Federal agency for health care research and quality.

31 (2) National institutes of health.

32 (3) National cancer institute.

33 (4) National academy of sciences.

34 (5) Centers for Medicare and Medicaid services.

35 (6) Federal food and drug administration.

1 (7) Any national board recognized by the national
2 institutes of health for the purpose of evaluating the medical
3 value of health care services.

4 f. Any other medical or scientific evidence that is
5 comparable to the sources listed in paragraphs "a" through "e".

6 27. "NAIC" means the national association of insurance
7 commissioners.

8 28. "Organized delivery system" means an entity system
9 authorized under 1993 Iowa Acts, ch. 158, and licensed by the
10 director of public health, and performing utilization review.

11 29. "Person" means an individual, a corporation, a
12 partnership, an association, a joint venture, a joint stock
13 company, a trust, an unincorporated organization, any similar
14 entity, or any combination of the foregoing.

15 30. "Protected health information" means health information
16 that meets either of the following descriptions:

17 a. Health information that identifies a covered person who
18 is the subject of the information.

19 b. Health information with respect to which there is a
20 reasonable basis to believe that the information could be used
21 to identify a covered person.

22 31. "Randomized clinical trial" means a controlled,
23 prospective study of patients that have been randomized into an
24 experimental group and a control group at the beginning of the
25 study with only the experimental group of patients receiving a
26 specific intervention, which includes study of the groups for
27 variables and anticipated outcomes over time.

28 Sec. 3. NEW SECTION. 514J.103 **Applicability and scope.**

29 1. Except as provided in subsection 2, this chapter shall
30 apply to all health carriers.

31 2. This chapter shall not apply to any of the following:

32 a. A policy or certificate that provides coverage only for a
33 specified disease, specified accident or accident-only, credit,
34 disability income, hospital indemnity, long-term care, dental
35 care, vision care, or any other limited supplemental benefit.

1 *b.* A Medicare supplement policy of insurance, as defined by
2 the commissioner by rule.

3 *c.* Coverage under a plan through Medicare, Medicaid, or the
4 federal employees health benefits program, any coverage issued
5 under 10 U.S.C. ch. 55, and any coverage issued as supplemental
6 to that coverage.

7 *d.* Any coverage issued as supplemental to liability
8 insurance.

9 *e.* Workers' compensation or similar insurance.

10 *f.* Automobile medical-payment insurance or any insurance
11 under which benefits are payable with or without regard to
12 fault, whether written on a group blanket or individual basis.

13 Sec. 4. NEW SECTION. 514J.104 **Notice of right to external**
14 **review.**

15 1. A health carrier shall notify a covered person or the
16 covered person's authorized representative, if known, in
17 writing of the covered person's right to request an external
18 review and include the appropriate statements and information
19 set forth in this chapter at the time the health carrier sends
20 written notice of a final adverse determination.

21 2. *a.* The notice shall include the following, or
22 substantially equivalent, language:

23 We have denied your request for the provision of or payment
24 for a health care service or course of treatment. You may
25 have the right to have our decision reviewed by health care
26 professionals who have no association with us if our decision
27 involved making a judgment as to the medical necessity,
28 appropriateness, health care setting, level of care, or
29 effectiveness of the health care service or treatment you
30 requested by submitting a request for external review to the
31 commissioner of insurance.

32 *b.* The notice shall include the current address and contact
33 information for the commissioner as specified in administrative
34 rule.

35 3. The health carrier shall include in the notice a

1 statement informing the covered person or the covered person's
2 authorized representative, if known, of the following:

3 *a.* If the covered person has a medical condition pursuant
4 to which the time frame for completion of a standard external
5 review would seriously jeopardize the life or health of the
6 covered person or would jeopardize the covered person's ability
7 to regain maximum function, the covered person or the covered
8 person's authorized representative may file a request for an
9 expedited external review.

10 *b.* If the final adverse determination concerns an admission,
11 availability of care, continued stay, or health care service
12 for which the covered person received emergency services, but
13 has not been discharged from a facility, the covered person or
14 the covered person's authorized representative may request an
15 expedited external review.

16 *c.* If the final adverse determination concerns a denial
17 of coverage based on a determination that the recommended or
18 requested health care service or treatment is experimental
19 or investigational as provided in section 514J.109, the
20 covered person may file a request for external review pursuant
21 to section 514J.109. In addition, if the covered person's
22 treating health care professional certifies in writing that
23 the recommended or requested health care service or treatment
24 that is the subject of the recommendation or request would
25 be significantly less effective if not promptly initiated,
26 the covered person or the covered person's authorized
27 representative may request an expedited external review
28 pursuant to section 514J.109, subsection 18.

29 4. The health carrier shall include with the notice a copy
30 of the descriptions of both the standard and expedited external
31 review procedures the health carrier is required to provide
32 pursuant to section 514J.116, highlighting the provisions in
33 the external review procedures that give the covered person or
34 the covered person's authorized representative the opportunity
35 to submit additional information and including any forms used

1 to process an external review.

2 5. The health carrier shall also include with the notice
3 an authorization form, or other document approved by the
4 commissioner that complies with the requirements of 45 C.F.R.
5 § 164.508 and with Tit. I of the federal Genetic Information
6 Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat.
7 881, by which the covered person or the covered person's
8 authorized representative authorizes the health carrier and
9 the covered person's treating health care provider to disclose
10 protected health information, including medical records,
11 concerning the covered person that is pertinent to the external
12 review.

13 Sec. 5. NEW SECTION. 514J.105 **Request for external review.**

14 A covered person or the covered person's authorized
15 representative may make a request for an external review of
16 a final adverse determination. Except for a request for an
17 expedited external review, all requests for external review
18 shall be made in writing to the commissioner. The commissioner
19 may prescribe by rule the form and content of external review
20 requests.

21 Sec. 6. NEW SECTION. 514J.106 **Exhaustion of internal
22 grievance process — exceptions — expedited external review
23 request.**

24 1. Except as otherwise provided in this section, a request
25 for an external review shall not be made until the covered
26 person or the covered person's authorized representative has
27 exhausted the health carrier's internal grievance process and
28 received a final adverse determination.

29 2. A covered person or the covered person's authorized
30 representative shall be considered to have exhausted the health
31 carrier's internal grievance process if the covered person or
32 the covered person's authorized representative has filed a
33 grievance involving an adverse determination and, except to the
34 extent the covered person or the covered person's authorized
35 representative requested or agreed to a delay, has not received

1 a written decision on the grievance from the health carrier
2 within thirty days following the date the covered person or the
3 covered person's authorized representative filed the grievance
4 with the health carrier.

5 3. A covered person or the covered person's authorized
6 representative may file a request for an expedited external
7 review of an adverse determination without exhausting the
8 health carrier's internal grievance process under either of the
9 following circumstances:

10 a. The covered person has a medical condition pursuant
11 to which the time frame for completion of an internal review
12 of the grievance involving an adverse determination would
13 seriously jeopardize the life or health of the covered person
14 or would jeopardize the covered person's ability to regain
15 maximum function as provided in section 514J.108.

16 b. The adverse determination involves a denial of
17 coverage based on a determination that the recommended or
18 requested health care service or treatment is experimental or
19 investigational and the covered person's treating physician
20 certifies in writing that the recommended or requested health
21 care service or treatment that is the subject of the adverse
22 determination would be significantly less effective if not
23 promptly initiated as provided in section 514J.109.

24 4. A request for an external review of an adverse
25 determination may be made before the covered person or the
26 covered person's authorized representative has exhausted the
27 health carrier's internal grievance procedures whenever the
28 health carrier agrees to waive the exhaustion requirement.
29 If the requirement to exhaust the health carrier's internal
30 grievance procedures is waived, the covered person or the
31 covered person's authorized representative may file a request
32 with the commissioner in writing for a standard external
33 review.

34 Sec. 7. NEW SECTION. 514J.107 External review — standard.

35 1. A covered person or the covered person's authorized

1 representative may file a written request for an external
2 review with the commissioner within four months after any of
3 the following events:

4 *a.* The date of receipt of a final adverse determination.

5 *b.* The failure of a health carrier to issue a written
6 decision within thirty days following the date the covered
7 person or the covered person's authorized representative filed
8 a grievance involving an adverse determination as provided in
9 section 514J.106, subsection 2.

10 *c.* The agreement of the health carrier to waive the
11 requirement that the covered person or the covered person's
12 authorized representative exhaust the health carrier's internal
13 grievance procedures before filing a request for external
14 review of an adverse determination as provided in section
15 514J.106, subsection 4.

16 2. Within one business day after the date of receipt of a
17 request for external review, the commissioner shall send a copy
18 of the request to the health carrier.

19 3. Within five business days following the date of receipt
20 of the external review request from the commissioner, the
21 health carrier shall complete a preliminary review of the
22 request to determine whether:

23 *a.* The individual is or was a covered person under the
24 health benefit plan at the time the health care service was
25 recommended or requested.

26 *b.* The health care service that is the subject of the
27 adverse determination or of the final adverse determination,
28 is a covered service under the covered person's health benefit
29 plan, but for a determination by the health carrier that the
30 health care service is not covered because it does not meet
31 the health carrier's requirements for medical necessity,
32 appropriateness, health care setting, level of care, or
33 effectiveness.

34 *c.* The covered person or the covered person's authorized
35 representative has exhausted the health carrier's internal

1 grievance process, unless the covered person or the covered
2 person's authorized representative is not required to exhaust
3 the health carrier's internal grievance process pursuant to
4 section 514J.106 or this section.

5 *d.* The covered person or the covered person's authorized
6 representative has provided all the information and forms
7 required to process an external review request.

8 4. Within one business day after completion of a preliminary
9 review pursuant to subsection 3, the health carrier shall
10 notify the commissioner and the covered person or the covered
11 person's authorized representative in writing whether the
12 request is complete and whether the request is eligible for
13 external review.

14 *a.* If the health carrier determines that the request is not
15 complete, the health carrier shall notify the covered person
16 or the covered person's authorized representative and the
17 commissioner in writing that the request is not complete and
18 what information or materials are needed to make the request
19 complete.

20 *b.* If the health carrier determines that the request is
21 not eligible for external review, the health carrier shall
22 issue a notice of initial determination in writing informing
23 the covered person or the covered person's authorized
24 representative and the commissioner of that determination
25 and the reasons the request is not eligible for review. The
26 health carrier shall also include a statement in the notice
27 informing the covered person or the covered person's authorized
28 representative that the health carrier's initial determination
29 of ineligibility may be appealed to the commissioner.

30 5. The commissioner may specify by rule the form required
31 for the health carrier's notice of initial determination and
32 any supporting information to be included in the notice.

33 6. The commissioner may determine that a request is eligible
34 for external review, notwithstanding a health carrier's initial
35 determination that the request is not eligible, and refer the

1 request for external review. In making this determination, the
2 commissioner's decision shall be made in accordance with the
3 terms of the covered person's health benefit plan and shall be
4 subject to all applicable provisions of this chapter.

5 7. Within one business day after receipt of notice from
6 a health carrier that a request for external review is
7 eligible for external review or upon a determination by the
8 commissioner that a request is eligible for external review,
9 the commissioner shall do all of the following:

10 a. Assign an independent review organization from the list
11 of approved independent review organizations maintained by the
12 commissioner and notify the health carrier of the name of the
13 assigned independent review organization. The assignment of
14 an independent review organization shall be done on a random
15 basis among those approved independent review organizations
16 qualified to conduct the particular external review based on
17 the nature of the health care service that is the subject of
18 the adverse determination or final adverse determination and
19 other circumstances, including conflict of interest concerns.

20 b. Notify the covered person or the covered person's
21 authorized representative in writing that the request is
22 eligible and has been accepted for external review including
23 the name of the assigned independent review organization and
24 that the covered person or the covered person's authorized
25 representative may submit in writing to the independent review
26 organization within five business days following receipt of
27 such notice from the commissioner, additional information
28 that the independent review organization shall consider
29 when conducting the external review. The independent review
30 organization may, in the organization's discretion, accept and
31 consider additional information submitted by the covered person
32 or the covered person's authorized representative after five
33 business days.

34 8. Within five business days after receipt of notice from
35 the commissioner pursuant to subsection 7, the health carrier

1 shall provide to the independent review organization the
2 documents and any information considered in making the adverse
3 determination or final adverse determination. Failure by the
4 health carrier to provide the documents and information within
5 the time specified shall not delay the conduct of the external
6 review.

7 9. If the health carrier fails to provide the documents
8 and information within the time specified, the independent
9 review organization may terminate the external review and
10 make a decision to reverse the adverse determination or final
11 adverse determination. Within one business day after making
12 such a decision, the independent review organization shall
13 notify the covered person or the covered person's authorized
14 representative, the health carrier, and the commissioner of its
15 decision.

16 10. The independent review organization shall review
17 all of the information and documents received pursuant to
18 subsection 8 and any other information submitted in writing
19 to the independent review organization by the covered person
20 or the covered person's authorized representative pursuant to
21 subsection 7, paragraph "b". Upon receipt of any information
22 submitted by the covered person or the covered person's
23 authorized representative, the independent review organization
24 shall, within one business day, forward the information to the
25 health carrier. In reaching a decision the independent review
26 organization is not bound by any decisions or conclusions
27 reached during the health carrier's internal grievance process.

28 11. Upon receipt of information forwarded pursuant to
29 subsection 10, a health carrier may reconsider its adverse
30 determination or final adverse determination that is the
31 subject of the external review.

32 a. Reconsideration by the health carrier of its
33 determination shall not delay or terminate the external review.
34 The external review shall only be terminated if the health
35 carrier decides, upon completion of its reconsideration, to

1 reverse its determination and provide coverage or payment for
2 the health care service that is the subject of the adverse
3 determination or final adverse determination.

4 *b.* Within one business day after making a decision
5 to reverse its adverse determination or final adverse
6 determination, the health carrier shall notify the covered
7 person or the covered person's authorized representative,
8 the independent review organization, and the commissioner in
9 writing of its decision. The independent review organization
10 shall terminate the external review upon receipt of notice
11 of the health carrier's decision to reverse its adverse
12 determination or final adverse determination.

13 12. In addition to the documents and information provided to
14 the independent review organization pursuant to this section,
15 the independent review organization shall, to the extent the
16 information or documents are available and the independent
17 review organization considers them appropriate, consider the
18 following in reaching a decision:

19 *a.* The covered person's pertinent medical records.

20 *b.* The treating health care professional's recommendation.

21 *c.* Consulting reports from appropriate health care
22 professionals and other documents submitted by the health
23 carrier, covered person, or the covered person's treating
24 physician or other health care professional.

25 *d.* The terms of coverage under the covered person's health
26 benefit plan with the health carrier, to ensure that the
27 independent review organization's decision is not contrary to
28 the terms of coverage under the covered person's health benefit
29 plan with the health carrier.

30 *e.* The most appropriate practice guidelines, which shall
31 include applicable evidence-based standards and may include any
32 other practice guidelines developed by the federal government,
33 national or professional medical societies, boards, and
34 associations.

35 *f.* Any applicable clinical review criteria developed and

1 used by the health carrier.

2 *g.* The opinion of the independent review organization's
3 clinical reviewer after considering the information or
4 documents described in paragraphs "a" through "f" to the extent
5 the information or documents are available and the clinical
6 reviewer considers them relevant.

7 13. *a.* Within forty-five days after the date of receipt
8 of a request for an external review, the independent review
9 organization shall provide written notice of its decision to
10 uphold or reverse the adverse determination or final adverse
11 determination of the health carrier to the covered person or
12 the covered person's authorized representative, the health
13 carrier, and the commissioner.

14 *b.* The independent review organization shall include in its
15 decision all of the following:

16 (1) A general description of the reason for the request for
17 external review.

18 (2) The date the independent review organization received
19 the assignment from the commissioner to conduct the external
20 review.

21 (3) The date the external review was conducted.

22 (4) The date of the decision.

23 (5) The principal reason or reasons for its decision,
24 including what applicable evidence-based standards, if any,
25 were a basis for its decision.

26 (6) The rationale for its decision.

27 (7) References to evidence or documentation, including
28 evidence-based standards, considered in reaching its decision.

29 14. Upon receipt of notice of a decision reversing the
30 adverse determination or final adverse determination of the
31 health carrier, the health carrier shall immediately approve
32 the coverage that was the subject of the determination.

33 **Sec. 8. NEW SECTION. 514J.108 External review — expedited.**

34 1. Notwithstanding section 514J.107, a covered person or
35 the covered person's authorized representative may make an

1 oral or written request to the commissioner for an expedited
2 external review at the time the covered person or the covered
3 person's authorized representative receives any of the
4 following:

5 *a.* An adverse determination that involves a medical
6 condition of the covered person for which the time frame for
7 completion of an internal review of a grievance involving an
8 adverse determination would seriously jeopardize the life or
9 health of the covered person or would jeopardize the covered
10 person's ability to regain maximum function.

11 *b.* A final adverse determination that involves a medical
12 condition where the time frame for completion of a standard
13 external review would seriously jeopardize the life or health
14 of the covered person or would jeopardize the covered person's
15 ability to regain maximum function.

16 *c.* A final adverse determination that concerns an admission,
17 availability of care, continued stay, or health care service
18 for which the covered person received emergency services, and
19 has not been discharged from a facility.

20 2. *a.* Upon receipt of a request for an expedited external
21 review, the commissioner shall immediately send written notice
22 of the request to the health carrier.

23 *b.* Immediately upon receipt of notice of a request for
24 expedited external review, the health carrier shall complete
25 a preliminary review of the request to determine whether the
26 request meets the eligibility requirements for external review
27 set forth in section 514J.107, subsection 3, and this section.

28 *c.* The health carrier shall then immediately issue a
29 notice of initial determination informing the commissioner
30 and the covered person or the covered person's authorized
31 representative of its eligibility determination including
32 a statement informing the covered person or the covered
33 person's authorized representative of the right to appeal that
34 determination to the commissioner.

35 *d.* The commissioner may specify by rule the form required

1 for the health carrier's notice of initial determination and
2 any supporting information to be included in the notice.

3 3. The commissioner may determine that a request is
4 eligible for expedited external review, notwithstanding a
5 health carrier's initial determination that the request is
6 not eligible. In making a determination, the commissioner's
7 decision shall be made in accordance with the terms of the
8 covered person's health benefit plan and shall be subject to
9 all applicable provisions of this chapter. The commissioner
10 shall make a determination pursuant to this subsection as
11 expeditiously as possible.

12 4. *a.* Upon receipt of notice from a health carrier
13 that a request is eligible for expedited external review or
14 upon a determination by the commissioner that a request is
15 eligible for expedited external review, the commissioner shall
16 immediately assign an independent review organization from the
17 list of approved independent review organizations maintained by
18 the commissioner to conduct the expedited external review. The
19 commissioner shall then immediately notify the health carrier
20 and the covered person or the covered person's authorized
21 representative of the name of the assigned independent review
22 organization.

23 *b.* The assignment of an independent review organization
24 shall be done on a random basis among those approved
25 independent review organizations qualified to conduct the
26 particular external review based on the nature of the health
27 care service that is the subject of the adverse determination
28 or final adverse determination and other circumstances,
29 including conflict of interest concerns.

30 5. Upon receiving notice of the independent review
31 organization assigned to conduct the expedited external review,
32 the health carrier shall provide or transmit all necessary
33 documents and information considered in making the adverse
34 determination or final adverse determination to the independent
35 review organization electronically or by telephone or facsimile

1 or any other available expeditious method.

2 6. The independent review organization is not bound
3 by any decisions or conclusions reached during the health
4 carrier's internal grievance process. The independent review
5 organization shall consider the documents and information
6 provided by the health carrier, and to the extent the
7 information or documents are available and the independent
8 review organization considers them appropriate, shall consider
9 the following in reaching a decision:

10 a. The covered person's pertinent medical records.

11 b. The treating health care professional's recommendation.

12 c. Consulting reports from appropriate health care
13 professionals and other documents submitted by the health
14 carrier, covered person or the covered person's authorized
15 representative, or the covered person's treating physician or
16 other health care professional.

17 d. The terms of coverage under the covered person's health
18 benefit plan with the health carrier, to ensure that the
19 independent review organization's decision is not contrary to
20 the terms of coverage under the covered person's health benefit
21 plan with the health carrier.

22 e. The most appropriate practice guidelines, which shall
23 include applicable evidence-based standards and may include any
24 other practice guidelines developed by the federal government,
25 national or professional medical societies, boards, and
26 associations.

27 f. Any applicable clinical review criteria developed and
28 used by the health carrier.

29 g. The opinion of the independent review organization's
30 clinical reviewer after considering the information or
31 documents described in paragraphs "a" through "f" to the extent
32 the information or documents are available and the clinical
33 reviewer considers them relevant.

34 7. a. As expeditiously as the covered person's medical
35 condition or circumstances require, but in no event more than

1 seventy-two hours after the date of receipt of an eligible
2 request for expedited external review, the assigned independent
3 review organization shall do all of the following:

4 (1) Make a decision to uphold or reverse the adverse
5 determination or final adverse determination of the health
6 carrier.

7 (2) Notify the covered person or the covered person's
8 authorized representative, the health carrier, and the
9 commissioner of its decision.

10 *b.* If the notice given by the independent review
11 organization pursuant to paragraph "a" was not in writing,
12 within forty-eight hours after providing that notice,
13 the independent review organization shall provide written
14 confirmation of the decision to the covered person or the
15 covered person's authorized representative, the health carrier,
16 and the commissioner that includes the information set forth in
17 section 514J.107, subsection 13, paragraph "b".

18 *c.* Upon receipt of the notice of decision by an independent
19 review organization pursuant to paragraph "a" reversing the
20 adverse determination or final adverse determination, the
21 health carrier shall immediately approve the coverage that
22 was the subject of the adverse determination or final adverse
23 determination.

24 **Sec. 9. NEW SECTION. 514J.109 External review of**
25 **experimental or investigational treatment adverse determinations.**

26 1. Within four months after the date of receipt of a notice
27 of an adverse determination or final adverse determination that
28 involves a denial of coverage based on a determination that
29 the health care service or treatment recommended or requested
30 is experimental or investigational, a covered person or the
31 covered person's authorized representative may file a request
32 for external review with the commissioner.

33 2. Within one business day after the date of receipt of the
34 request, the commissioner shall notify the health carrier of
35 the request.

1 3. Within five business days following the date of receipt
2 of notice of a request for external review pursuant to this
3 section, the health carrier shall complete a preliminary review
4 of the request to determine whether:

5 a. The individual is or was a covered person under the
6 health benefit plan at the time the health care service or
7 treatment was recommended or requested.

8 b. The recommended or requested health care service or
9 treatment that is the subject of the adverse determination or
10 final adverse determination meets the following conditions:

11 (1) Is a covered benefit under the covered person's health
12 benefit plan except for the health carrier's determination that
13 the service or treatment is experimental or investigational for
14 a particular medical condition.

15 (2) Is not explicitly listed as an excluded benefit under
16 the covered person's health benefit plan with the health
17 carrier.

18 c. The covered person's treating physician has certified
19 that one of the following situations is applicable:

20 (1) Standard health care services or treatments have
21 not been effective in improving the condition of the covered
22 person.

23 (2) Standard health care services or treatments are not
24 medically appropriate for the covered person.

25 (3) There is no available standard health care service or
26 treatment covered by the health carrier that is more beneficial
27 than the recommended or requested health care service or
28 treatment sought.

29 d. The covered person's treating physician has certified in
30 writing one of the following:

31 (1) That the recommended or requested health care service
32 or treatment that is the subject of the adverse determination
33 or final adverse determination is likely to be more beneficial
34 to the covered person, in the physician's opinion, than any
35 available standard health care services or treatments.

1 (2) The physician is a licensed, board-certified, or
2 board-eligible physician qualified to practice in the area of
3 medicine appropriate to treat the covered person's condition,
4 and that scientifically valid studies using accepted protocols
5 demonstrate that the health care service or treatment
6 recommended or requested that is the subject of the adverse
7 determination or final adverse determination is likely to
8 be more beneficial to the covered person than any available
9 standard health care services or treatments.

10 e. The covered person or the covered person's authorized
11 representative has exhausted the health carrier's internal
12 grievance process, unless the covered person or the covered
13 person's authorized representative is not required to exhaust
14 the health carrier's internal grievance process pursuant to
15 section 514J.106 or 514J.108.

16 f. The covered person or the covered person's authorized
17 representative has provided all the information and forms
18 required by the commissioner that are necessary to process an
19 external review pursuant to this section.

20 4. Within one business day after completion of the
21 preliminary review pursuant to subsection 3, the health
22 carrier shall notify the commissioner and the covered person
23 or the covered person's authorized representative in writing
24 whether the request is complete and whether the request is
25 eligible for external review pursuant to this section. If the
26 request is not complete, the health carrier shall notify the
27 commissioner and the covered person or the covered person's
28 authorized representative in writing and include in the notice
29 what information or materials are needed to make the request
30 complete. If the request is not eligible for external review,
31 the health carrier shall notify the covered person or the
32 covered person's authorized representative and the commissioner
33 in writing and include in the notice the reasons for its
34 ineligibility.

35 5. The commissioner may specify by rule the form required

1 for the health carrier's notice of initial determination and
2 any supporting information to be included in the notice. The
3 notice of initial determination shall include a statement
4 informing the covered person or the covered person's authorized
5 representative that a health carrier's initial determination
6 that the external review request is ineligible for review may
7 be appealed to the commissioner.

8 6. The commissioner may determine that a request is eligible
9 for external review pursuant to this section, notwithstanding
10 a health carrier's initial determination that the request
11 is ineligible, and require that it be referred for external
12 review. In making this determination, the commissioner's
13 decision shall be made in accordance with the terms of the
14 covered person's health benefit plan and shall be subject to
15 all applicable provisions of this chapter.

16 7. Within one business day after receipt of the notice
17 from the health carrier that the external review request is
18 eligible for external review or upon a determination by the
19 commissioner that a request is eligible for external review,
20 the commissioner shall do all of the following:

21 a. Assign an independent review organization from the list
22 of approved independent review organizations maintained by the
23 commissioner and notify the health carrier of the name of the
24 assigned independent review organization.

25 b. Notify the covered person or the covered person's
26 authorized representative in writing of the request's
27 eligibility and acceptance for external review and the
28 name of the assigned independent review organization and
29 that the covered person or the covered person's authorized
30 representative may submit in writing to the independent review
31 organization, within five business days following the date
32 of receipt of such notice, additional information that the
33 independent review organization shall consider when conducting
34 the external review. The independent review organization
35 may, in the organization's discretion, accept and consider

1 additional information submitted by the covered person or the
2 covered person's authorized representative after five business
3 days.

4 8. Within one business day after receipt of the notice
5 of assignment to conduct the external review, the assigned
6 independent review organization shall select one or more
7 clinical reviewers, as it determines is appropriate pursuant to
8 subsection 9 to conduct the external review.

9 9. In selecting clinical reviewers, the independent review
10 organization shall select physicians or other health care
11 professionals who meet the minimum qualifications described in
12 this chapter and, through clinical experience in the past three
13 years, are experts in the treatment of the covered person's
14 condition and knowledgeable about the recommended or requested
15 health care service or treatment that is the subject of the
16 adverse determination or the final adverse determination.
17 Neither the covered person or the covered person's authorized
18 representative nor the health carrier shall choose or control
19 the choice of the clinical reviewers selected to conduct the
20 external review.

21 10. Each clinical reviewer selected shall provide a written
22 opinion to the independent review organization regarding
23 whether the recommended or requested health care service or
24 treatment should be covered. Each clinical reviewer shall
25 review all of the information and documents received and any
26 other information submitted in writing by the covered person or
27 the covered person's authorized representative. In reaching
28 an opinion, a clinical reviewer is not bound by any decisions
29 or conclusions reached during the health carrier's internal
30 grievance process.

31 11. Within five business days after receipt of notice of the
32 assignment of the independent review organization, the health
33 carrier shall provide to the independent review organization
34 the documents and any information considered in making the
35 adverse determination or the final adverse determination.

1 Failure by the health carrier to provide the documents and
2 information within the time specified shall not delay the
3 conduct of the external review.

4 12. If the health carrier fails to provide the documents
5 and information within the time specified, the independent
6 review organization may terminate the external review and
7 make a decision to reverse the adverse determination or final
8 adverse determination. Within one business day after making
9 such a decision, the independent review organization shall
10 notify the covered person or the covered person's authorized
11 representative, the health carrier, and the commissioner.

12 13. Within one business day after the receipt of any
13 information submitted by the covered person or the covered
14 person's authorized representative, the independent review
15 organization shall forward the information to the health
16 carrier. Upon receipt of the forwarded information, the health
17 carrier may reconsider its adverse determination or final
18 adverse determination that is the subject of the external
19 review.

20 *a.* Reconsideration by the health carrier of its adverse
21 determination or final adverse determination shall not delay or
22 terminate the external review. The external review shall only
23 be terminated if the health carrier decides, upon completion
24 of its reconsideration, to reverse its determination and
25 provide coverage or payment for the recommended or requested
26 health care service or treatment that is the subject of the
27 determination.

28 *b.* Within one business day after making a decision to
29 reverse its determination, the health carrier shall notify
30 the covered person or the covered person's authorized
31 representative, the independent review organization, and the
32 commissioner in writing of its decision. The independent
33 review organization shall terminate the external review upon
34 receipt of such notice from the health carrier.

35 14. *a.* Within twenty days after being selected to conduct

1 the external review, each clinical reviewer shall provide
2 an opinion to the assigned independent review organization
3 regarding whether the recommended or requested health care
4 service or treatment should be covered pursuant to this
5 section.

6 *b.* Each clinical reviewer's opinion shall be in writing and
7 include the following information:

8 (1) A description of the covered person's medical
9 condition.

10 (2) A description of the indicators relevant to determining
11 whether there is sufficient evidence to demonstrate that the
12 recommended or requested health care service or treatment is
13 likely to be more beneficial to the covered person than any
14 available standard health care services or treatments and that
15 the adverse risks of the recommended or requested health care
16 service or treatment would not be substantially increased over
17 those of available standard health care services or treatments.

18 (3) A description and analysis of any medical or scientific
19 evidence considered in reaching the opinion.

20 (4) A description and analysis of any applicable
21 evidence-based standards.

22 (5) Information on whether the reviewer's rationale for
23 the opinion is based on either of the factors described in
24 subsection 15, paragraph "e".

25 15. In addition to the documents and information provided,
26 each clinical reviewer, to the extent the information or
27 documents are available and the reviewer considers them
28 appropriate, shall consider all of the following in reaching
29 an opinion:

30 *a.* The covered person's pertinent medical records.

31 *b.* The treating physician's recommendation or request.

32 *c.* Consulting reports from appropriate health care
33 professionals and other documents submitted by the health
34 carrier, the covered person or the covered person's authorized
35 representative, or the covered person's treating physician or

1 other health care professional.

2 *d.* The terms of coverage under the covered person's health
3 benefit plan with the health carrier to ensure that, but
4 for the health carrier's determination that the recommended
5 or requested health care service or treatment that is the
6 subject of the opinion is experimental or investigational, the
7 reviewer's opinion is not contrary to the terms of coverage
8 under the covered person's health benefit plan with the health
9 carrier.

10 *e.* Whether either of the following factors is applicable:

11 (1) The recommended or requested health care service or
12 treatment has been approved by the federal food and drug
13 administration, if applicable, for the condition.

14 (2) Medical or scientific evidence or evidence-based
15 standards demonstrate that the expected benefits of the
16 recommended or requested health care service or treatment is
17 likely to be more beneficial to the covered person than any
18 available standard health care service or treatment and the
19 adverse risks of the recommended or requested health care
20 service or treatment would not be substantially increased over
21 those of available standard health care services or treatments.

22 16. *a.* If a majority of the clinical reviewers opine that
23 the recommended or requested health care service or treatment
24 should be covered, the independent review organization shall
25 make a decision to reverse the health carrier's adverse
26 determination or final adverse determination.

27 *b.* If a majority of the clinical reviewers opine that the
28 recommended or requested health care service or treatment
29 should not be covered, the independent review organization
30 shall make a decision to uphold the health carrier's adverse
31 determination or final adverse determination.

32 *c.* If the clinical reviewers are evenly split as to whether
33 the recommended or requested health care service or treatment
34 should be covered, the independent review organization shall
35 obtain the opinion of an additional clinical reviewer in order

1 for the independent review organization to make a decision
2 based on the opinions of a majority of the clinical reviewers.

3 *d.* The additional clinical reviewer selected shall use the
4 same information to reach an opinion as the clinical reviewers
5 who have already submitted their opinions.

6 *e.* The selection of an additional clinical reviewer under
7 this subsection shall not extend the time within which the
8 assigned independent review organization is required to make a
9 decision based on the opinions of the clinical reviewers for
10 the external review.

11 17. Within twenty days after it receives the opinion
12 of each clinical reviewer, the assigned independent review
13 organization shall make a decision based on the opinions of
14 the clinical reviewer or reviewers, to uphold or reverse the
15 adverse determination or final adverse determination of the
16 health carrier and provide written notice of the decision
17 to the covered person or the covered person's authorized
18 representative, the health carrier, and the commissioner.

19 18. *a.* A covered person or the covered person's authorized
20 representative may make a written or oral request to the
21 commissioner for an expedited external review of the adverse
22 determination or final adverse determination pursuant to
23 this subsection if the covered person's treating physician
24 certifies, in writing, that the recommended or requested
25 health care service or treatment that is the subject of the
26 request would be significantly less effective if not promptly
27 initiated.

28 (1) Upon receipt of a request for an expedited external
29 review pursuant to this subsection, the commissioner shall
30 immediately notify the health carrier.

31 (2) Upon receipt of notice of the request for expedited
32 external review, the health carrier shall immediately determine
33 whether the request is eligible for external review as
34 provided in subsection 3, paragraphs "a" through "f", and shall
35 immediately issue a notice of initial determination informing

1 the commissioner and the covered person or the covered person's
2 authorized representative of its eligibility determination.
3 The notice of initial determination of eligibility issued by a
4 health carrier shall include a statement informing the covered
5 person or the covered person's authorized representative that
6 the health carrier's initial determination that the external
7 review request is ineligible for expedited external review may
8 be appealed to the commissioner.

9 (3) The commissioner may determine that a request is
10 eligible for external review, notwithstanding a health
11 carrier's initial determination that the request is not
12 eligible, and refer the request for external review. In making
13 this determination, the commissioner's decision shall be made
14 in accordance with the terms of the covered person's health
15 benefit plan and shall be subject to all applicable provisions
16 of this chapter.

17 *b.* (1) Upon receipt of the notice of initial determination
18 that the request is eligible for expedited external review
19 or upon a determination by the commissioner that the request
20 is eligible for expedited external review, the commissioner
21 shall immediately assign an independent review organization
22 to conduct the expedited external review, from the list of
23 approved independent review organizations maintained by the
24 commissioner, and notify the health carrier of the name of the
25 assigned independent review organization.

26 (2) Upon receipt of notice of the independent review
27 organization assigned to conduct an expedited external review,
28 the health carrier shall provide or transmit all necessary
29 documents and information considered in making the adverse
30 determination or final adverse determination to the independent
31 review organization electronically or by telephone or facsimile
32 or any other available expeditious method.

33 (3) A clinical reviewer or clinical reviewers shall be
34 selected immediately by the independent review organization and
35 shall provide an opinion orally or in writing to the assigned

1 independent review organization as expeditiously as the covered
2 person's medical condition or circumstances require, but in no
3 event more than five calendar days after being selected. If
4 the opinion provided was not in writing, within forty-eight
5 hours following the date the opinion was provided, the clinical
6 reviewer shall provide written confirmation of the opinion to
7 the assigned independent review organization and include all
8 required information in support of the opinion.

9 *c.* Within forty-eight hours after the date of receipt
10 of the opinion of each clinical reviewer, the assigned
11 independent review organization shall make a decision based
12 on the opinions of the clinical reviewer or reviewers as to
13 whether to reverse or uphold the adverse determination or
14 final adverse determination and provide notice of the decision
15 orally or in writing to the covered person or the covered
16 person's authorized representative, the health carrier, and
17 the commissioner. If the notice was provided orally, within
18 forty-eight hours after the date of providing that notice,
19 the independent review organization shall provide written
20 confirmation of the decision to the covered person or the
21 covered person's authorized representative, the health carrier,
22 and the commissioner.

23 *d.* The independent review organization shall include in the
24 notice of its decision all of the following:

25 (1) A general description of the reason for the request for
26 an expedited external review.

27 (2) The written opinion of each clinical reviewer,
28 including the recommendation of each clinical reviewer as
29 to whether the recommended or requested health care service
30 or treatment should be covered and the rationale for the
31 reviewer's recommendation.

32 (3) The date the independent review organization was
33 assigned by the commissioner to conduct the expedited external
34 review.

35 (4) The date the expedited external review was conducted.

1 (5) The date of its decision.

2 (6) The principal reason or reasons for its decision.

3 (7) The rationale for its decision.

4 19. Upon receipt of notice of a decision of the independent
5 review organization reversing an adverse determination or final
6 adverse determination, the health carrier shall immediately
7 approve coverage of the recommended or requested health care
8 service or treatment that was the subject of the determination.

9 Sec. 10. NEW SECTION. 514J.110 **Effect of external review**
10 **decision.**

11 1. An external review decision pursuant to this chapter is
12 binding on the health carrier except to the extent the health
13 carrier has other remedies available under applicable Iowa law.
14 The external review process shall not be considered a contested
15 case under chapter 17A.

16 2. *a.* A covered person or the covered person's authorized
17 representative may appeal the external review decision made by
18 an independent review organization by filing a petition for
19 judicial review either in Polk county district court or in
20 the district court in the county in which the covered person
21 resides. The petition for judicial review must be filed
22 within fifteen business days after the issuance of the review
23 decision. The petition shall name the covered person or the
24 covered person's authorized representative, or the person's
25 health care provider as the petitioner. The respondent
26 shall be the health carrier. The petition shall not name the
27 independent review organization as a party.

28 *b.* The commissioner shall not be named as a respondent
29 unless the petitioner alleges action or inaction by the
30 commissioner under the standards articulated in section
31 17A.19, subsection 10. Allegations against the commissioner
32 under section 17A.19, subsection 10, shall be stated with
33 particularity. The commissioner may, upon motion, intervene in
34 the judicial review proceeding. The findings of fact by the
35 independent review organization conducting the external review

1 are conclusive and binding on appeal.

2 3. The health carrier shall follow and comply with the
3 decision of the court on appeal. The health carrier or
4 treating health care provider shall not be subject to any
5 penalties, sanctions, or award of damages for following and
6 complying in good faith with the external review decision of
7 the independent review organization or the decision of the
8 court on appeal.

9 4. The covered person or the covered person's authorized
10 representative may bring an action in Polk county district
11 court or in the district court in the county in which the
12 covered person resides to enforce the external review decision
13 of the independent review organization or the decision of the
14 court on appeal.

15 5. A covered person or the covered person's authorized
16 representative shall not file a subsequent request for external
17 review involving any determination for which the covered person
18 or the covered person's authorized representative has already
19 received an external review decision.

20 6. If a covered person dies before the completion of
21 the external review process, the process shall continue to
22 completion if there is potential liability of a health carrier
23 to the estate of the covered person.

24 7. *a.* If a covered person who has already received health
25 care services under a health benefit plan requests external
26 review of the plan's adverse determination or final adverse
27 determination and changes to another health benefit plan before
28 the external review process is completed, the health carrier
29 whose coverage was in effect at the time the health care
30 service was received is responsible for completing the external
31 review process.

32 *b.* If a covered person who has not yet received health
33 care services requests external review of a health benefit
34 plan's adverse determination or final adverse determination
35 and then changes to another plan prior to receipt of the

1 health care services and completion of the external review
2 process, the external review process shall begin anew with the
3 covered person's current health carrier. In this instance,
4 the external review process shall be conducted as an expedited
5 external review.

6 Sec. 11. NEW SECTION. 514J.111 **Approval of independent**
7 **review organizations.**

8 1. The commissioner shall approve applications submitted by
9 independent review organizations to conduct external reviews
10 under this chapter. The commissioner may retain an outside
11 expert to perform reviews of such applications.

12 2. In order to be eligible for approval by the commissioner
13 to conduct external reviews, an independent review organization
14 shall meet all of the following requirements:

15 a. Be accredited by a nationally recognized private
16 accrediting entity that the commissioner determines has
17 independent review organization accreditation standards that
18 are equivalent to or exceed the minimum qualifications for
19 independent review organizations established in this chapter.

20 b. Submit an application in a form and format as directed by
21 the commissioner.

22 c. Meet the minimum qualifications contained in section
23 514J.112.

24 3. The commissioner may approve independent review
25 organizations that are not accredited by a nationally
26 recognized private accrediting entity if there are no
27 acceptable nationally recognized private accrediting entities
28 providing independent review organization accreditation.

29 4. The commissioner shall develop an application form for
30 initially approving and for reapproving independent review
31 organizations to conduct external reviews.

32 5. The commissioner may charge an initial application fee
33 and a renewal fee as specified by rule.

34 6. The approval of an independent review organization to
35 conduct external reviews by the commissioner pursuant to this

1 chapter is effective for two years, unless the commissioner
2 determines that the independent review organization is not
3 satisfying the minimum qualifications of this chapter. If the
4 commissioner determines that an independent review organization
5 has lost its accreditation or no longer satisfies the minimum
6 requirements established under this chapter, the commissioner
7 shall terminate approval of the independent review organization
8 to conduct external reviews and remove the independent review
9 organization from the list of independent review organizations
10 approved to conduct external reviews that is maintained by the
11 commissioner.

12 7. The commissioner shall maintain a list of currently
13 approved independent review organizations.

14 Sec. 12. NEW SECTION. 514J.112 **Minimum qualifications for**
15 **independent review organizations.**

16 1. To be approved to conduct external reviews pursuant
17 to this chapter, an independent review organization shall
18 have and maintain written policies and procedures that govern
19 all aspects of both the standard external review process and
20 the expedited external review process and that include, at a
21 minimum, all of the following:

22 a. A quality assurance mechanism that does all of the
23 following:

24 (1) Ensures that external reviews are conducted within the
25 specified time frames and that required notices are provided
26 in a timely manner.

27 (2) Ensures the selection of qualified and impartial
28 clinical reviewers to conduct external reviews on behalf of
29 the independent review organization and suitable matching of
30 reviewers to specific cases and that the independent review
31 organization employs or contracts with an adequate number of
32 clinical reviewers to meet this objective.

33 (3) Ensures the confidentiality of medical and treatment
34 records and clinical review criteria.

35 (4) Establishes and maintains written procedures to

1 ensure that the independent review organization is unbiased in
2 addition to any other procedures required under this section.

3 (5) Ensures that any person employed by or under contract
4 with the independent review organization adheres to the
5 requirements of this chapter.

6 *b.* A toll-free telephone service to receive information
7 related to external reviews twenty-four hours a day, seven days
8 a week, that is capable of accepting, recording, or providing
9 appropriate instruction to incoming telephone callers outside
10 normal business hours.

11 *c.* An agreement and a system to maintain required records
12 and provide access to those records by the commissioner.

13 2. Each clinical reviewer assigned by an independent review
14 organization to conduct external reviews shall be a physician
15 or other appropriate health care professional who meets all of
16 the following minimum qualifications:

17 *a.* Is an expert in the treatment of the covered person's
18 medical condition that is the subject of the external review.

19 *b.* Is knowledgeable about the recommended or requested
20 health care service or treatment through recent or current
21 actual clinical experience treating patients with the same or
22 similar medical condition as the covered person.

23 *c.* Holds a nonrestricted license in a state of the United
24 States and, for physicians, a current certification by a
25 recognized American medical specialty board in the area or
26 areas appropriate to the subject of the external review.

27 *d.* Has no history of disciplinary actions or sanctions,
28 including loss of staff privileges or participation
29 restrictions, that have been taken or are pending by any
30 hospital, governmental agency or unit, or regulatory body that
31 raise a substantial question as to the clinical reviewer's
32 physical, mental, or professional competence or moral
33 character.

34 3. An independent review organization shall not own
35 or control, be a subsidiary of, or in any way be owned or

1 controlled by, or exercise control with, a health benefit plan,
2 a national, state, or local trade association of health benefit
3 plans, or a national, state, or local trade association of
4 health care providers.

5 4. Neither the independent review organization selected to
6 conduct an external review nor any clinical reviewer assigned
7 by the independent organization to conduct an external review
8 shall have a material professional, familial, or financial
9 conflict of interest with any of the following:

10 a. The health carrier that is the subject of the external
11 review.

12 b. The covered person whose health care service or treatment
13 is the subject of the external review or the covered person's
14 authorized representative.

15 c. Any officer, director, or management employee of the
16 health carrier that is the subject of the external review.

17 d. The health care professional or the health care
18 professional's medical group or independent practice
19 association recommending the health care service or treatment
20 that is the subject of the external review.

21 e. The facility at which the recommended health care service
22 or treatment would be provided.

23 f. The developer or manufacturer of the principal drug,
24 device, procedure, or other therapy being recommended for the
25 covered person whose health care service treatment is the
26 subject of the external review.

27 5. In determining whether an independent review
28 organization or a clinical reviewer of the independent
29 review organization has a material professional, familial,
30 or financial conflict of interest as provided in subsection
31 4, the commissioner shall take into consideration situations
32 where the independent review organization to be assigned to
33 conduct an external review of a specified case or a clinical
34 reviewer to be assigned by the independent review organization
35 to conduct an external review of a specified case may have an

1 apparent professional, familial, or financial relationship or
2 connection with a person described in subsection 4, but the
3 characteristics of that relationship or connection are such
4 that they do not constitute a material professional, familial,
5 or financial conflict of interest that would prohibit selection
6 of the independent review organization or the clinical reviewer
7 to conduct the external review.

8 6. a. An independent review organization that is accredited
9 by a nationally recognized private accrediting entity that
10 has independent review accreditation standards that the
11 commissioner has determined are equivalent to or exceed the
12 minimum qualifications of this section shall be presumed to be
13 in compliance with the requirements of this section.

14 b. The commissioner shall initially and periodically review
15 the standards of each nationally recognized private accrediting
16 entity that provides accreditation to independent review
17 organizations to determine whether the accrediting entity's
18 standards are, and continue to be, equivalent to or exceed the
19 minimum qualifications established under this section. The
20 commissioner may accept a review of those standards conducted
21 by the national association of insurance commissioners for the
22 purpose of making a determination under this subsection.

23 c. Upon request, a nationally recognized private accrediting
24 entity shall make its current independent review organization
25 accreditation standards available to the commissioner or
26 to the national association of insurance commissioners in
27 order for the commissioner to determine if the accrediting
28 entity's standards are equivalent to or exceed the minimum
29 qualifications established under this section. The
30 commissioner may exclude consideration of accreditation of
31 independent review organizations by any private accrediting
32 entity whose standards have not been reviewed by the national
33 association of insurance commissioners.

34 Sec. 13. NEW SECTION. 514J.113 Immunity for independent
35 review organizations.

1 An independent review organization, a clinical reviewer
2 working on behalf of an independent review organization, or
3 an employee, agent, or contractor of an independent review
4 organization shall not be liable in damages to any person for
5 any opinions rendered or acts or omissions performed within the
6 scope of the duties of the organization, the clinical reviewer,
7 or an employee, agent, or contractor of the organization under
8 this chapter during, or upon completion of, an external review
9 conducted pursuant to this chapter, unless the opinion was
10 rendered or the act or omission was performed in bad faith or
11 involved gross negligence.

12 Sec. 14. NEW SECTION. 514J.114 External review reporting
13 requirements.

14 1. a. An independent review organization assigned to
15 conduct an external review shall maintain written records in
16 the aggregate by state and by health carrier of all requests
17 for external review for which it conducted an external review
18 during a calendar year.

19 b. Each independent review organization required to maintain
20 written records pursuant to this section shall submit to the
21 commissioner, upon request, a report in the format specified by
22 the commissioner. The report shall include in the aggregate by
23 state and by health carrier all of the following:

24 (1) The total number of requests for external review
25 assigned to the independent review organization.

26 (2) The average length of time for resolution of each
27 request for external review assigned to the independent review
28 organization.

29 (3) A summary of the types of coverages or cases for which
30 an external review was requested, in the format required by the
31 commissioner by rule.

32 (4) Any other information required by the commissioner.

33 c. The independent review organization shall retain the
34 written records for at least three years.

35 2. a. Each health carrier shall maintain written records

1 in the aggregate by state and by type of health benefit plan
2 offered by the health carrier of all requests for external
3 review that the health carrier receives notice of from the
4 commissioner pursuant to this chapter.

5 *b.* Each health carrier required to maintain written records
6 of requests for external review pursuant to this subsection
7 shall submit to the commissioner, upon request, a report in the
8 format specified by the commissioner. The report shall include
9 in the aggregate by state and by type of health benefit plan
10 offered all of the following:

11 (1) The total number of requests for external review of
12 the health carrier's adverse determinations and final adverse
13 determinations.

14 (2) Of the total number of requests for external review, the
15 number of requests determined eligible for external review.

16 (3) The number of requests for external review resolved
17 and, of those resolved, the number resolved upholding the
18 adverse determination or final adverse determination of the
19 health carrier and the number resolved reversing the adverse
20 determination or final adverse determination of the health
21 carrier.

22 (4) The number of external reviews that were terminated as
23 the result of a reconsideration by the health carrier of its
24 adverse determination or final adverse determination after the
25 receipt of additional information from the covered person or
26 the covered person's authorized representative.

27 (5) Any other information the commissioner may request or
28 require.

29 *c.* The health carrier shall retain the written records for
30 at least three years.

31 Sec. 15. NEW SECTION. 514J.115 **Expenses of external review.**

32 The health carrier against which a request for a standard
33 external review or an expedited external review is filed shall
34 pay the costs of retaining an independent review organization
35 to conduct the external review.

1 Sec. 16. NEW SECTION. 514J.116 **Disclosure requirements.**

2 1. Each health carrier shall include a description of
3 the external review procedures contained in this chapter in
4 or attached to any policy, certificate, membership booklet,
5 outline of coverage, or other evidence of coverage that is
6 provided to a covered person. The description shall be in a
7 format prescribed by the commissioner by rule.

8 2. The description required by subsection 1 shall include
9 a statement that informs the covered person of the right of
10 the covered person to file a request for an external review
11 of an adverse determination or final adverse determination of
12 the health carrier with the commissioner. The statement shall
13 explain that external review is available when the adverse
14 determination or final adverse determination involves an issue
15 of medical necessity, appropriateness, health care setting,
16 level of care, or effectiveness. The statement shall include
17 the telephone number and address of the commissioner. The
18 statement shall also inform the covered person that when filing
19 a request for external review, the covered person will be
20 required to authorize the release of any medical records of
21 the covered person that may be required to be reviewed for the
22 purpose of reaching a decision on the request for external
23 review.

24 Sec. 17. NEW SECTION. 514J.117 **Rulemaking authority.**

25 The commissioner may adopt rules pursuant to chapter 17A to
26 carry out the provisions of this chapter.

27 Sec. 18. NEW SECTION. 514J.118 **Severability.**

28 If any provision of this chapter, or the application of the
29 provision to any person or circumstance is held invalid, the
30 remainder of the chapter, and the application of the provision
31 to persons or circumstances other than those to which it is
32 held invalid, shall not be affected.

33 Sec. 19. NEW SECTION. 514J.119 **Penalties.**

34 A person who fails to comply with the provisions of this
35 chapter or the rules adopted pursuant to this chapter is

1 subject to the penalties provided under chapter 507B.

2 Sec. 20. NEW SECTION. 514J.120 **Applicability.**

3 1. This chapter applies to all requests for external review
4 filed on or after July 1, 2011.

5 2. Section 514J.116 applies to all health benefit plans
6 delivered, issued for delivery, continued, or renewed in this
7 state on or after July 1, 2011.

8 Sec. 21. **REPEAL.** Sections 514J.1 through 514J.15, Code
9 2011, are repealed.

10 Sec. 22. **TRANSITION PROVISION — APPLICABILITY TO PRIOR**
11 **REQUESTS.** Sections 514J.1 through 514J.15, Code 2011, are
12 applicable to all requests for external review filed prior to
13 July 1, 2011.